

**REMARKS**

In the Office Action, the Examiner rejected Claims 14-17 under the provisions of 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,845,255 to Mayaud (hereinafter “the ‘255 Patent” or “Mayaud”). In doing so, the Examiner stated that Mayaud teaches a method of creating and using product recall information including, *inter alia*, “accessing product data information at the time of administering institutionally dispensed medication, combinations of medications, and/or patient-specific prepared medications by an authorized person to an institutionally based patient.

Claim 14 is directed to a method of creating and using product recall information, including accessing product recall information for manufactured products, creating a recall information database, updating the database in real time, disseminating the information to institutionally-based local data repositories at health care institutions via the Internet and accessing the information at the time of administering institutionally dispensed medication by an authorized person to an institutionally based patient.

In keeping, it is an essential step of the claimed method that the product recall information be accessed at the time of administering institutionally dispensed medication by an authorized person to an institutionally based patient. This system ensures that critical information is available on a real time basis at the time of administration of a drug or combination of drugs to an institutional patient.

Applicant respectfully states that Mayaud does not teach this step, as found in subparagraph (e) of Claim 14, on which Claims 15-17 also depend. In this regard, the Examiner’s citations to Mayaud for this step fail to teach the particular step.

Mayaud is directed to an “electronic prescription pad” where a prescribing physician accesses information on a drug or combination of drugs at the time the drugs are **prescribed**, not when administered to the institutionally based patient. Of course, this information does not guarantee that the warnings or recalls after the prescription is written but prior to the administration to the patient will be discovered.

The Examiner's first citation to Mayaud for the step of subparagraph (e) is to the Abstract. However, the Abstract makes no mention of the time of administration to an institutionally based patient. Rather, the Abstract merely speaks to a "prescription **creation** system . . . which captures **into a prescription**" certain information (emphasis added). The Abstract concludes by noting extension to "physician to pharmacy and physician to physician" communication. There is no reference whatsoever in the Abstract to the accessing of the information at the time of administration of the of the medication to the institutionally based patient.

Next the Examiner cites to column 1, lines 46-52 of Mayaud for subparagraph (e) of Claim 14. However, this sentence merely discusses the information that is frequently unavailable to and/or unobtainable by a **prescribing** physician unless that physician's institution or organization has been exhaustively responsible for that patient's prior care and maintains sophisticated computerized records. There is no teaching at this citation that the information be available to **administering** personnel at the time of administration. Nothing in this citation deals with anything more that information of a particular patient at the time of prescription of the medication. Since the step of subparagraph (e) deals with administration, not prescription, the citation fails to teach the claimed step.

The next citation by the Examiner for the claimed step of subparagraph (e) is to column 2, lines 65-67 continuing to column 3, lines 1-19. This citation states that clinical physicians are not necessarily deskbound and fill roles at various locations. The following passages go on to state that recent computing devices provide a mobile source of information and that an objective of the invention of Mayaud is therefore "to provide a prescription management system that can be used by physicians on such mobile computing devices." The only teaching from this citation is that physicians can be at the location of administration during a busy day, but **without any teaching whatsoever to use the information system at the time of administration** as presently claimed. The statement of the object of the invention summing up the citation makes the lack of

teaching regarding the time of administration clear, so that teaching of the step of subparagraph (e) is not found in the citation.

The Examiner next cited column 4, lines 22-43 for the step of subparagraph (e). However, this citation repeatedly discusses the problem and solution relating to the availability of information at the time of prescription, even referring to the “quality of the **prescription written**” and “whereby in **creating** said prescription said prescriber specifies a patient condition for treatment by said prescribed drug” (emphasis added). Nowhere in the cited section is the use of information at the time of **administration** even remotely suggested, much less taught. In fact, there is no thought whatsoever in the citation as to use of information at the time of administration of the medication, discussing only the time of writing or creating the prescription.

Next the Examiner cited to column 5, lines 5-32 and lines 45-48 of Mayaud for the step of subparagraph (e) of Claim 14. The first section deals only with a posting means to capture a prescription, a procedure for creating a prescription, a drug selection procedure with possible prescribable drugs to select and tracking means to adapt to the user’s (prescriber’s) habits. However, each element of the system described deals only with the prescription of the drug according to the patient’s condition and the prescriber’s preference for dealing with the condition. There is absolutely nothing in the first section of this citation that hints at, much less teaches, accessing product information at the time of **administration** of medication to an institutionally based patient.

Similarly, the second section of this citation, to column 5, lines 45-48, also refers to determining which medications to prescribe for a particular condition. Significantly, when referring to “user” of the system, Mayaud is referring to the prescribing physician or pharmacist, not the patient (see column 4, lines 22-43). Therefore, the second section of the citation only describes that the information used in prescribing medication be available on a real time basis. However, no mention whatsoever is made to accessing product data information at the time of administration.

The next citation by the Examiner for the subject step of subparagraph (e) of Claim 14 is to column 30, lines 11-24 of Mayaud. This citation actually teaches away

from a step where authorized personnel access product data information in real time at the time of administration of a medication to an institutionally based patient, as defined in Claim 14. More particularly, the citation deals with preparing drug packaging for a patent to **“take with them to their home or on their travels”** (emphasis added). Thus, there is nothing whatsoever about accessing product data by authorized personnel for an institutional patient, making the cited description from Mayaud diametrically opposed to the claimed step.

Additionally, the only information provided in this portion of the Mayaud reference is whether “drugs, pills, capsules or the like have been removed”, not the product data information referred to in subparagraph (e) of Claim 14. Thus, the citation entirely fails to teach the subject step of subparagraph (e).

The last citation by the Examiner for the step of subparagraph (e) of Claim 14 is to column 47, lines 47-53 of Mayaud. This citation deals with updating product information in the Mayaud system, which is still directed to the prescribing physician/pharmacist. Again, as with the prior citations, there is absolutely no teaching to access this information at the time of administration of medication to an institutionally based patient.

Since there is no teaching for accessing product information by authorized personnel at the time of administering medication to an institutionally based patient, the Mayaud reference fails to anticipate the invention of Claim 14. Removal of the rejection to Claims 14-17, and an indication of allowance thereof, is therefore respectfully requested.

The Examiner also rejected Claims 1, 3-5, 7-13 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Mayaud in view of Lester et al., United States Patent No. 6,021,392 (hereinafter “Lester”). In making this rejection to Claim 1, the Examiner stated that “Mayaud teaches a secure, Internet-based universal data repository system for medical product information . . . for dissemination of information . . . upon administration by an authorized person to institutional based patients (See column 1, lines 46-52; column 4, lines 22-43; column 5, lines 5-32) . . .” In making this rejection to

independent Claim 12, the Examiner cited to Mayaud column 1, lines 46-52; column 4, lines 22-43; column 5, lines 5-32, lines 45-48; column 30, lines 11-24; and column 47, lines 47-53. As such, the Examiner relies on the same citations to Mayaud for the system requirements of Claim 1 and the method steps of Claim 12, on which the remaining claims depend, as to the elements of the step of subparagraph (e) of Claim 14 discussed in detail above.

For the same reasons as set forth above, applicant respectfully states that Mayaud does not teach or suggest the use of real time product data information by authorized personnel at the time of administration of the medication to an institutionally based patient, as required in Claim 1. Since each of the citations were individually discussed above, and were shown to lack any teaching or suggestion of accessing or disseminating product information to authorize personnel upon administration of the medication to an institutionally based patient, there is no need to restate the discussion here. The above discussion makes clear that Mayaud fails as a reference as to the claimed subject matter.

Moreover, combination with Lester does not cure the deficiency of Mayaud. Lester is directed to a system and method for drug management, and more particularly a method to inventory drugs. Nowhere does Lester even remotely hint at disseminating or accessing real time information on product data information at the time of administration by authorized personnel to an institutionally based patient. Of course, the Examiner, recognizing that Lester does not suggest such an element or step, does not cite Lester for this purpose.

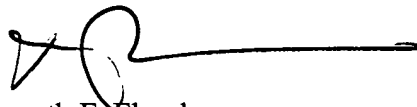
Notwithstanding, for a *prima facie* case of obviousness to be established, the teachings from the prior art itself must have suggested the claimed subject matter to one of ordinary skill in the art. The mere fact that the prior art could be modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness.

The present case provides no suggestion or motivation (express or implied) based on Lester or Mayaud to combine the prescription system of Mayaud with the inventory system of Lester, as they are wholly unrelated functions. Of course, even if combined,

albeit improperly, the combination fails to teach or suggest the present claimed invention, as set forth above.

In light of the foregoing, applicant respectfully submits that the pending claims of the present application are patentable over the cited references. Favorable consideration and an indication of allowance of the claims is therefore respectfully requested and earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, consisting of a stylized 'K' followed by a horizontal line.

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